



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,743	02/14/2002	Royce Johnson	VAC.700	1606
7590	11/19/2003		EXAMINER	
Kinetic Concepts, Inc. P.O. Box 659508 San Antonio, TX 78265-9508			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/19/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/075,743	JOHNSON ET AL.
Examiner	Art Unit	
Kim M. Lewis	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: *Detailed Action*.

DETAILED ACTION

Power Of Attorney

1. The Power of Attorney paper filed 2/14/02 has been received and made of record in the application file wrapper.

Priority

2. If applicant desires priority under 35 U.S.C. 119 (e) based upon a previously filed application, specific reference to the earlier filed application by ***correct application number and filing date*** must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the

application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

The applicant should note that the examiner acknowledges applicant's request for priority to a previously filed provisional application, however, the provisional

application number listed in the application data sheet and on the second line of the specification of the present invention is incorrect.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

4. The disclosure is objected to because of the following informalities:

Page 1, line 4, after "7" insert --,--;

Page 15, line 9, "bioabsorbalbe" should read --bioabsorbable--;

On page 10, lines 18-23, the applicant recites that the collagen matrix is replaced, then later recites that the collagen matrix is absorbed. It is unclear how it is both replaced and absorbed. It appears to the examiner that this is a typo and should be corrected; and

Page 11, in Example IV, the applicant recites that one or more or more similar materials are placed on a conventional pad (referring to materials presented in US patents), then recites that the collagen matrix is absorbed. How is the collagen matrix

Art Unit: 3761

absorbed when the applicant has not stated that the pad contains collagen? This again appears to be a typo.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the applicant claims "[t]he biocompatible wound dressing of claim 2 further comprising an open-cell reticulated porous foam adhered to non-wound contacting surfaces of said ceramic". This is neither described in the specification nor clear from the present written description how the foam is adhered to non-wound contacting surfaces of the ceramic.

Claim 4 is necessarily rejected as being dependent upon rejected claim 3.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/05873 ("Lina et al").

As regards claim 1, Lina et al. disclose all features of the claimed invention including a porous foamed pad (36) shaped to conform to a wound (page 8, last paragraph), an air-tight seal (wound cover 43) adhered to the skin and/or pad (page 8, 2nd full paragraph), and a negative pressure source (vacuum pump 84) in fluid communication with the pad (page 9, 1st full paragraph).

As to the biocompatibility of the pad, since the pad can be placed on or within a wound cavity, the pad is inherently biocompatible. Also, on page 7, starting with the 3rd full paragraph, Lina et al. disclose the pad as being constructed from open cell polyurethane or polyether foam, both of which is biocompatible.

As to the removability of the air-tight seal (wound cover) from the pad, the examiner contends that the disclosed acrylic adhesive is capable of being removably attached to the pad in the same manner that it is removably attached to the skin.

As regards claim 5, Lina et al. disclose that the pad is connected via hoses (37, 38) to a canister (19) and that the canister is connected to the pump. As can be read the last line on page 7, the hoses are preferably made from medical grade PVC tube. This tubing is inherently flexible.

As to claim 6, Lina et al. disclose that the canister is placed within recess (18) and can be removed therefrom (page 13, 2nd full paragraph).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 2-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of US Patent Application Publication No. 2003/0077311 A1 ("Vyakarnam et al.") and U.S. Patent No. 5,621,035 ("Lyles et al.)

13. As regards claims 2 and 7, note the rejection of claim 1 above. In further regard to claims 2 and 7, Lina et al. substantially disclose the invention as claimed except for an ultra-low density fused-fibrous ceramic.

Vyakarnam et al., however, disclose that it is known to apply bioabsorbable polymer foams to various areas of the body in order to promote tissue regeneration. Further disclosed is the use of a ceramic in combination with the foam in order to reinforce the foam such that the foam is strengthened so as to be structurally compatible with cancellous bone (col. 4, lines 2-7).

Vyakarnam et al. fail to teach that the type of ceramic used is an ultra-low density fused-fibrous ceramic. However, Lyles et al. disclose the use of ultra-low density fused-fibrous ceramic. Lyles et al. teach that ultra-low density fused-fibrous ceramic have various desirable properties, such as for example, high tensile strength, dimensional stability, low thermal conductivity, etc. (col. 3, lines 30-63).

It would have been obvious to one having ordinary skill in the art to provide the foam pad of Lina et al. with a ceramic in order to strengthen the foam as taught by Vyakarnam et al.

It would have also been obvious to one having ordinary skill in the art to substitute the ceramic disclosed in Vyakarnam et al. for the ultra-low density fused-fibrous ceramic disclosed in Lyles et al., since Lyles et al. disclose that the ultra-low density fused-fibrous ceramic have additional desired properties such as high tensile strength, dimensional stability, low thermal conductivity, etc.

As regards claim 3, the foam disclosed in Lina et al. is an open-cell reticulated foam (page 7, last paragraph and page 8, 2nd full paragraph). Once modified and placed on/in a wound of a user, all of the foam does not touch the wound, see Fig. 10. Therefore, some of the ceramic particles will not touch the wound (*i.e.*, the foam is adhered to non-wound contacting surfaces of the ceramic).

As regards claim 4, the modified pad of Lina et al. as discussed in the rejection of claims 2 and 7 above, is removable from the ceramic in that it is bioabsorbable.

As regards claim 8, note the rejection of claim 5 above.

As regards claim 9, note the rejection of claim 6 above.

14. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al.

As regards claim 10, Lina et al. substantially disclose all the features of the claimed invention including a pad comprised of branched polymers (polyurethane or polyether foam). Lina et al. fails to teach a pad comprised of biosorbable branched polymers.

Vyakarnam et al. disclose a foam composite comprised of biosorbable branched polymers because they are particularly well suited for tissue engineering (abstract and paragraph 50).

It would have been obvious to one having ordinary skill in the art to substitute the foam pad of Lina et al. with a foam pad comprised of a bioabsorbable foam because they are particularly well suited for tissue engineering, as taught by Vyakarnam et al.

As regards claim 11, note the rejection of claim 5 above.

As regards claim 12, note the rejection of claim 6 above.

15. Claim 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of 4,614,794 (Easton et al.").

As regards claim 13, Lina et al. substantially disclose all features of the claim except that the pad comprises a cell-growth enhancing matrix. However, Easton et al. disclose a wound dressing (pad) comprising the biodegradable protein collagen, thereby teaching a cell-growth enhancing matrix for enhancing cellular growth.

It would have been obvious to one having ordinary skill in the art to add the wound dressing (pad) of Easton et al. to the pad of Lina et al. in order to enhance or improve cellular growth at the wound site. The applicant should note that Easton et al. teach that the wound dressing can be used in conjunction with conventional absorbents (col. 6, lines 41-47)

As regards claim 14, note the rejection of claim 5 above.

As regards claim 15, note the rejection of claim 6 above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday to Wednesday from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



**Kim M. Lewis
Primary Examiner
Art Unit 3761**

kml
November 10, 2003